UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

NOVO NORDISK, INC., Plaintiff, v. DCA PHARMACY, Defendant.	)))))))))	Case No. 3:23-cv-668 District Judge Crenshaw Jury Demand

DEFENDANT DCA PHARMACY, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS[1]

[1] Defendant is of the belief that it is permitted to file this second basis for motion to dismiss under Fed R. Civ. P. 12(b) as on January 23, 2024, this Court granted Defendant's motion to withdraw its first motion to dismiss for mootness. Because this court withdrew Defendant's motion prior to ruling on that motion, Defendant holds the belief that it is permitted to file a second motion to dismiss. Nevertheless, if this Court disagrees that Defendant is permitted to make this motion, Defendant intends to file an answer and convert this motion into a Fed R. Civ. P. 12(c) motion, which may be made at any time after the close of pleadings. Fed. R. Civ. P. 12(c) & 12(h)(2)(B).

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Defendant, DCA Pharmacy, Inc. ("Defendant"), submits this motion to dismiss on the ground that Plaintiff Novo Nordisk, Inc., ("Plaintiff" or "Novo Nordisk") lacks standing to bring this state law-based litigation and that its sole claim is preempted by applicable Federal Law. As a threshold matter, it is clear that Plaintiff fails to allege any cognizable injury, and therefore lacks standing. Nevertheless, even if this Court deems that Plaintiff has standing, its sole claim in this action is not only speculative, but also preempted by applicable Federal Law. Therefore Plaintiff's Complaint, ECF No. 1 (the "Complaint") must be dismissed.[2]

FACTUAL BACKGROUND

The Complaint alleges that Defendant, DCA Pharmacy, Inc. ("Defendant"), is in violation of Tennessee's Consumer Protection Act ("TCPA"), which prohibits selling illegal goods or services. Complaint at ¶10. Plaintiff's sole allegation that Defendant is selling "illegal" goods or services is that Defendant is distributing drugs in violation of Tenn. Code Ann. § 53-1-110, which specifies that "no person shall sell, deliver, offer for sale, hold for sale or give away any new drug" unless it is approved under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Tenn. Code Ann. § 53-1-110.

The procedures for approval of new drugs under the FDCA are found at 21 U.S.C. §355, which prohibits "introducing" or "delivering for introduction" any "new drug" into interstate commerce unless it is approved pursuant to its terms. However, omitted by Plaintiff in its allegation is that there is an exemption for "pharmacy compounding," in which §355 *does not* apply to any drug which is compounded by a licensed pharmacist for an individual patient with a prescription

[2] Defendant believes that preemption is an issue of subject-matter jurisdiction and is therefore framing this motion as a motion under FRCP 12(b)(1). However, if this Court disagrees, Defendant requests that this Court treat Defendant's motion as one for failure to state a claim under FRCP 12(b)(6). Defendant believes that because this action is manifestly preempted by applicable appellate caselaw, further adjudication would merely be a waste of judicial time and resources.

made by a licensed physician, *or* if the pharmacist has an "established relationship" with a prescribing physician or individual patient and a history of prescribing that drug for that patient. 21 U.S.C. §353a(a). Furthermore, a drug product may only be compounded if a pharmacist (1) compounds it using applicable safety standards, either promulgated in Pharmacopoeias or by the secretary, (2) "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product," and (3) if the drug product is not on a list of dangerous drugs to compound as promulgated by the Secretary. 21 U.S.C. §353a. The Food and Drug Administration ("FDA") is authorized to create the rules and regulations necessary to implement section 503A. 21 U.S.C. §§ 353a(c).

Pursuant to its statutory authority to implement the FDCA, the FDA has promulgated a "shortage list."[3] Critically, when a drug is on the FDA's "shortage list," the FDA does not consider it a "commercially available drug product"[4] which would otherwise be prohibited from being "regularly [compounded] or in inordinate amounts." 21 U.S.C. §353a(b)(1)(d). As of May 2022, Semaglutide is on the FDA's drug shortages list.[5] Semaglutide continues to be on the FDA's drug shortage list and is therefore specifically permitted to be compounded by the FDA as of January 10, 2024.[6]

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[3] Ordinarily, a court may not consider extrinsic evidence outside the pleadings without converting a motion to dismiss into one for summary judgment. "However, a court may consider…public records…so long as they are referred to in the complaint and are central to the claims contained therein without converting the motion to one for summary judgment." *Rondigo, L.L.C. v. Twp. of Richmond*, 641 F.3d 673, 680–81 (6th Cir. 2011) (internal quotations omitted). Given the fact that Plaintiff's complaint directly references Novo Nordisk's FDA approval of its semaglutide product (Complaint at ¶29) it is facially obvious that FDA regulations regarding semaglutide are both referred in and integral to the Complaint.

[4] *See* FDA, "Drug Compounding and Drug Shortages" https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-and-drug-shortages (accessed January 22, 2024) ("FDA does not consider a drug to be commercially available when it appears on FDA's drug shortages list.")

[5] *See* FDA Online Drug Shortage List, "Semaglutide Injection" https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Semaglutide%20Injection&st=c (accessed January 22, 2024)

[6] *See* FDA, "Medications Concerning Semaglutide Marketed for Type 2 Diabetes or Weight Loss" https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss (accessed January 22, 2024)

LEGAL STANDARD

There are differing burdens of proof and standards for resolving factual issues depending on whether a Defendant files a motion to dismiss for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) or Fed. R. Civ. P. 12(b)(6): "When subject matter jurisdiction is challenged under Rule 12(b)(1), the plaintiff has the burden of proving jurisdiction in order to survive the motion. In addition, the district court is empowered to resolve factual disputes when necessary to resolve challenges to subject matter jurisdiction." *Madison-Hughes v. Shalala*, 80 F.3d 1121, 1130 (6th Cir. 1996) (internal citations and quotations omitted). On the other hand, in addressing a motion to dismiss for failure to state a claim "the Court must construe the complaint in the light most favorable to the plaintiff and accept all well-pled factual allegations as true…Nonetheless, a complaint must contain sufficient facts 'to state a claim to relief that is plausible on its face'" to survive a motion to dismiss." *Williams v. United States*, 754 F. Supp. 2d 942, 946 (W.D. Tenn. 2010) (*quoting Ashcroft v. Iqbal,* 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009)).

What is clear, however, regarding both a defense of a lack of subject matter jurisdiction and failure to state a claim is that *neither* is waived by failing to bring them up in a motion to dismiss in lieu of an answer. *See* Fed. R. Civ. P. 12(h)("A party waives any defense listed in Rule 12(b)(2)–(5) [by failing to include it in a motion to dismiss]…[however,]Failure to state a claim upon which relief can be granted…may be raised: (A) in any pleading allowed or ordered under Rule 7(a);(B) by a motion under Rule 12(c); or (C) at trial."). Further, at any time, this Court may determine *sua sponte* that it lacks subject-matter jurisdiction and must dismiss the complaint. *See* Fed R. Civ. P. 12(h)(3)("If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.").

ARGUMENT

I. Plaintiff Lacks Standing

It is axiomatic that a litigant requires Article III standing to pursue a claim. *California v. Texas*, 141 S. Ct. 2104, 2113, 210 L. Ed. 2d 230 (2021). ("The Constitution gives federal courts the power to adjudicate only genuine 'Cases' and 'Controversies. [which] power includes the requirement that litigants have standing."). In order to satisfy Article III standing, a litigant must allege that "1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and 3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Lalaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 180–81, 120 S. Ct. 693, 704, 145 L. Ed. 2d 610 (2000). A plaintiff bears the burden of establishing these elements. *Id.*

However, there is a further requirement for standing when a litigant pursues injunctive relief, as Plaintiff does here. In those circumstances, a plaintiff must not only demonstrate that it *has* suffered an injury-in-fact but must also have a demonstration of a real and immediate threat that the harmful conduct "will occur in the future [is] required for injunctive relief." *Kanuszewski v. Michigan Dep't of Health & Hum. Servs.*, 927 F.3d 396, 406 (6th Cir. 2019) (*quoting City of Los Angeles v. Lyons*, 461 U.S. 95, 106, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983)). Further, "Obtaining standing for declaratory relief has the same requirements as obtaining standing for injunctive relief." *Id.* Lastly, "At the pleadings stage, a plaintiff "must 'clearly … allege facts demonstrating' each element." *Id*.

Plaintiff has not demonstrated standing, because Plaintiff fails to demonstrate an "injury in fact" fairly traceable to the "challenged conduct." Plaintiff's Complaint alleges "Defendant markets and sells to patients certain drug products that purport to contain 'semaglutide' and are

not FDA approved" (Complaint at ¶9) and that "Defendant's unfair competition jeopardizes public health," (*Id.,* at ¶17) but fails to link that to harm to *Plaintiff.* Plaintiff conclusively alleges harm to its goodwill and reputation, but the Complaint alleges no facts with which one could reasonably ascertain such harm to Plaintiff resulting from Defendant's conduct. There are no allegations that Defendant used Plaintiff's trademarks, trade names, or branding. Indeed, there are no links between Plaintiff and Defendant *at all,* except for the fact that they both sell drugs using the semaglutide molecule.

The only possible harm alleged by Plaintiff traceable to Defendant is "an ascertainable loss in the form of lost customers…" (¶40). However, the FDA *specifically* permits pharmacies, such as Defendant, to compound semaglutude, because it is currently in a shortage.[7] Plaintiff has no inherent right to any customers, as Defendant is not selling anything trademarked, copyrighted, or patented by Plaintiff. Indeed, the only harm that Plaintiff alleges is merely *competition,* which is legitimate and, indeed, explicitly greenlit by applicable FDA regulators. *Compare* Complaint at ¶9 ("Defendant markets and sells to patients certain drug products that purport to contain 'semaglutide' and are not FDA approved") *with* FDA.Gov, Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss (Content Current as of 1/10/2024) ("Compounded drugs are not FDA-approved… When a drug is in shortage, compounders may be able to prepare a compounded version of that drug if they meet certain requirements in the Federal Food, Drug, and Cosmetic (FD&C) Act. As of May 2023, Ozempic and Wegovy are both listed on FDA's Drug Shortages list."). [8]

[7] "Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss" https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss

[8] *Id.*

Except for legitimate competition allowed by the FDA, Plaintiff has utterly failed to aver any claims of past or future harm that would satisfy the elements of standing for injunctive and declaratory relief. Therefore, the Complaint should be dismissed.

II. Plaintiff's Claim is Preempted by the FDCA

The Supremacy Clause of the United States Constitution makes clear that "the Laws of the United States ... shall be the supreme Law of the Land..." U.S. Const. art. VI, cl. 2. Flowing from this clause of the Constitution, it is well settled that when Congress passes a law, it supersedes all state or local ordinances that either explicitly or implicitly conflict with it. When Congress passed the FDCA in 1938, it created the FDA and it imbued that agency with the responsibility for investigating and prosecuting violations of the FDA. 21 U.S.C. §§ 332-34, 372. The FDCA also made enforcement power under the FDCA exclusive to the Federal Government: "[e]xcept as provided in subsection b, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a); *see also POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) ("[T]he FDCA and its regulations provide the United States with nearly exclusive enforcement authority, including the authority to seek criminal sanctions in some circumstances."); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349, 121 S. Ct. 1012, 1018, 148 L. Ed. 2d 854 (2001)("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions").

However, of note herein, Plaintiff in this case did not sue under Federal law, rather, its sole cause of action is for violation of a state statute that prohibits selling "illegal" goods in the State of Tennessee. Plaintiff's sole support for the claim that Defendant is selling "illegal" goods is that Defendant is allegedly selling goods in violation of Tenn. Code Ann. § 53-1-110, which directly

references the FDCA. *See* Tenn. Code Ann. § 53-1-110. ("No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the federal act."[9]). Thus, Plaintiff is suing under a state law extension of the FDCA. In other words, Plaintiff's premise is that state law can override federal law, which conflicts with the Constitution.

The Supreme Court squarely addressed the question of whether a similar state court action was precluded by the FDCA in *Buckman,* where the Supreme Court held that the FDCA preempted the plaintiff from asserting a state court action against a medical device manufacturer where the plaintiff alleged that the device manufacturer had committed fraud when gaining FDA approval for their medical device. *See Buckman,* 531 U.S. at 352-53. The Supreme Court's decision rested on the grounds that the FDCA imbued the FDA with a variety of enforcement mechanisms over suspected violations of the FDA and that "[t]his flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives… the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals. State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 349-350.

In order to balance the competing interests of a federal regulatory scheme and the right of affected plaintiffs to seek relief, the Supreme Court created a bright line test between causes of action that "exist solely by virtue of the FDCA disclosure requirements" and "traditional state tort law which had predated the federal enactments in question." *Id.* At 353. The Supreme Court

[9] The relevant Tennessee Code chapter definition states "Federal act means the federal Food, Drug and Cosmetic Act, compiled at 21 U.S.C. § 301 et seq., as amended." Tenn. Code Ann. § 53-1-10(13).

expounded that the claims in *Buckman* were precluded because "the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." *Id.*

So too, is it with the case at hand. Plaintiff's claim is not of a "traditional state law tort" that would exist absent the FDCA as the state statute that it is predicated on *directly references the FDCA*. Indeed, the Sixth Circuit has already addressed an analogous situation partially dismissing claims under New Jersey's consumer protection laws on the grounds that certain of them werepreempted by the FDCA in *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 578–79 (6th Cir. 2013). In *Loreto*, the plaintiffs alleged violations of New Jersey consumer protection laws on two different theories, firstly, that Procter & Gamble had sold products that were illegal under New Jersey's consumer protection law by virtue of not complying with FDCA labeling violation, and secondly that Procter & Gamble had advertised for its products in a false or misleading matter. The Sixth Circuit distinguished between these two kinds of claims on the theory below

> "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with" its substantive provisions… The statute's public enforcement mechanism is thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA. Under principles of "implied preemption," therefore, private litigants may not bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA…
>
> The question, then, is how to determine whether a claim formally asserted under state law is in substance one seeking to enforce the FDCA. The Supreme Court supplied the test in *Buckman:* If the claim would not exist in the absence of the FDCA, it is impliedly preempted. In other words:
>
> > [T]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—**and that would give rise to liability under state law even if the FDCA had never been enacted.** If the defendant's conduct is

> not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman.*

Loreto v. Procter & Gamble Co., 515 F. App'x 576, 578–79 (6th Cir. 2013) (emphasis added and internal citations and quotations omitted). *See also White v. Medtronic, Inc.*, 808 F. App'x 290, 294 (6th Cir. 2020) (holding that a plaintiff's state law claims against a medical device manufacturer that had manufactured a device that allegedly caused grievous harm to his deceased wife for *inter alia*, "violations of Michigan's consumer protection laws," "were impliedly preempted… because they existed 'solely by virtue' of an FDCA violation."). Therefore, the Sixth Circuit in *Loreto* held that certain of the plaintiffs' claims were preempted specifically, that:

> Plaintiffs allege that Procter & Gamble omitted telling consumers that its products were "illegal," and had plaintiffs known it, they wouldn't have purchased the products. The products were illegal, plaintiffs maintain, because their labeling did not comply with the FDCA's requirements. This theory of liability depends entirely upon an FDCA violation—*i.e.,* the *only* reason Procter & Gamble's products were allegedly "illegal" was because they failed to comply with FDCA labeling requirements. The theory is impliedly preempted by federal law.

Loreto, 515 F. App'x at 579. On the other hand, the Sixth Circuit held that plaintiffs' other theory, that Procter & Gamble had "included plaintiffs to purchase the [false and misleading] advertised products" was *not* preempted, because "this theory relies solely on traditional state tort law predating the FDCA…" *Id.*

In the case at hand, however, Plaintiff's *sole* cause of action is that "Defendant is engaged in unlawful and unfair business and trade practices because Defendant manufactures and dispenses its Unapproved New Drugs in violation of the Tennessee Food, Drug & Cosmetic Act. This law prohibits the sale of new drugs unless the drugs are approved by FDA" (Complaint at ¶13), a crystal-clear state law extension of the FDCA if there ever was one. *Loreto* perfectly illustrates the distinction between Plaintiff's claim in this case and "traditional common law claims.". Because

there is absolutely no chance that Defendant's alleged actions would "give rise to liability under state law even if the FDCA had never been enacted," (*Loreto,* 515 F. App'x at 578) it must be dismissed.[10]

CONCLUSION

For all the above reasons, specifically that Plaintiff lacks standing and that its sole claim is preempted by the FDCA, Plaintiff's complaint should be dismissed.

Respectfully Submitted,

/s/Marc O. Dedman

Marc O. Dedman (TN #014044)
BARTON LLP
611 Commerce Street
Suite 2603
Nashville, TN 37203
Telephone: (615) 340-6790
mdedman@bartonesq.com

Attorney for Defendant DCA Pharmacy

[10] Indeed, of particular note herein, a sister court in the Middle District of Florida dismissed a complaint by this same plaintiff, Novo Nordisk, against a Tampa Pharmacy involving these same issues on the grounds that "Plaintiff's claim, as written, is that Plaintiff suffers economic loss due to Defendant's violation of the Florida Drug and Cosmetic Act, which is itself a law that says in substance comply with the FDCA. The Court can identify no alleged conduct that would give rise to liability under state law even if the [FDCA] did not exist. To survive a motion to dismiss, Plaintiff must plead factual content that allows the Court to infer the breach of a well-recognized duty owed to [Plaintiff] under state law." *Novo Nordisk, Inc. v. Brooksville Pharms. Inc.*, No. 8:23-CV-1503-WFJ-TGW, 2023 WL 7385819, at *3 (M.D. Fla. Nov. 8, 2023) (internal citations and quotations omitted).

CERTIFICATE OF SERVICE

I certify that, on January 31, 2024, I filed the foregoing document via the Court's electronic filing system, which will automatically notify and send a copy of the filing to:

Steven A. Riley
Milton S. McGee III
Joseph K. Robinson
RILEY & JACOBSON, PLC

Joseph N. Akrotirianakis
Aaron Craig
KING & SPALDING

Attorneys for Plaintiffs

/s/Marc O. Dedman
Marc O. Dedman (TN #014044)
Attorney for Defendant DCA Pharmacy